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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,331	03/29/2004	Bill J. Peck	10031531-1	5115

22878 7590 03/24/2006

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EXAMINER

MUMMERT, STEPHANIE KANE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/813,331	Applicant(s) PECK ET AL.	
	Examiner Stephanie K. Mummert	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to a method of producing an array of nucleic acid ligands, classified in class 435, subclass 6.
 - II. Claims 17, 22-23, drawn to a kit comprising a nucleic acid array, classified in class 536, subclass 24.3.
 - III. Claims 18-21, drawn to a method of nucleic acid detection, classified in class 536, subclass 23.1.
 - IV. Claims 24-27, drawn to an apparatus for synthesizing an array, classified in class 425, subclass 288.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the nucleic acid array can be made by applying pre-synthesized nucleic oligonucleotides to defined locations on a solid support to form an oligonucleotide array with the same features as claimed in the method of group I. To fully search both the nucleic acid array of group II and the method of producing the array of group I, would require separate searches of the specific method recited in group I and a search of arrays which meet the limitations of the final product of the method,

Art Unit: 1637

including methods which do not incorporate the use of oxidation fluids. Therefore, because these searches are distinct and do not encompass the same review of the prior art, it would pose an undue burden on the examiner to require a search of both of these inventions together.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to distinct methods with different reagents, different method steps and different end products. The method of group III is directed to a method of nucleic acid detection, while the method of group I is directed to a method of producing an oligonucleotide array. These methods have distinct modes of operation and each require a separate search of the prior art. For example, a search of the method of group II would address nucleic acid arrays but would not necessarily address the synthesis of the array before the array was used in the method of group III. In the alternative, a search of the method of producing an array would not necessarily address the methods of using the array. Therefore, because these separate searches encompass different search terms and are not coextensive, it would pose an undue burden on the examiner to require a search of both of these inventions together.

4. Inventions I and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of group I can be practiced using an apparatus which spots oligonucleotides on specific locations within the larger array, a process which is known in the art of microarray manufacture. An

Art Unit: 1637

apparatus of this kind would be distinct from the apparatus described in group IV. Because the array can be manufactured using apparatus' distinct from the apparatus described in group IV, it would be necessary to search both the method of manufacture and the apparatus separately.

These searches would require separate searches of the prior art, directed to both methods of array manufacture and to apparatus' for array manufacture, searches which are not coextensive in scope and which would not necessarily include the same or similar search terms. Therefore, to require a search of these separate inventions together would pose an undue burden on the examiner.

5. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid array of group II can be used to capture biomolecules which interact with the nucleic acids found within the array, such as DNA binding proteins. Therefore, because the array is distinct from the method of using the array, to fully search both the method of detection of group II and the nucleic acid array of group III would require separate and distinct searches of the prior art. These searches would require distinct terms directed to the nucleic acid array itself and also to methods of detection using microarray platforms. Therefore, because distinct searches of the prior art are necessary for both the array of group II and the method of group III, it would pose an undue burden on the examiner to require a search of both of these inventions together.

Art Unit: 1637

6. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to separate and distinct inventions which have different modes of operation, different designs and result in different effects. The invention of group II is directed to a nucleic acid array, while the invention of group IV is directed to an apparatus which manufactures arrays. While the two inventions share an array in common, a search of the nucleic acid array of group II would not address apparatus' for the manufacture of arrays. In the reverse situation, a search of the prior art addressing apparatus' would not necessarily address the nucleic acid array of group II. Therefore, because these two inventions are distinct and require separate searches of the prior art which are not coextensive, it would pose an undue burden on the examiner to require a search of both the apparatus and the array together.

7. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are directed to separate and distinct inventions which have different modes of operation, different designs and result in different effects. The invention of group III is directed to a method of detection, while the invention of group IV is directed to an apparatus for synthesizing an array. While the two groups of inventions share an array in common, a search of apparatus' for the manufacture of arrays would not necessarily address the method of detection of group III. In the reverse situation, a search of the method of detection of group II would not necessarily address the apparatus' for manufacture of certain oligonucleotide arrays. Therefore, because these two

Art Unit: 1637

inventions are distinct and require separate searches of the prior art which are not coextensive, it would pose an undue burden on the examiner to require a search of both the apparatus and the array together.

8. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Art Unit: 1637

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

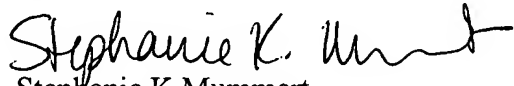
Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1637

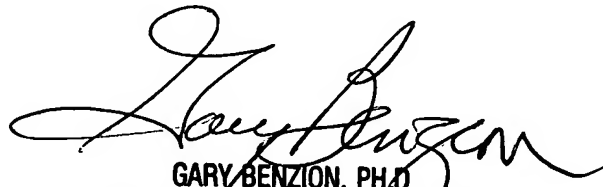
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie K. Mummert whose telephone number is 571-272-8503. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0872. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Stephanie K Mummert
Examiner
Art Unit 1637

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